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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,532	03/19/2004	Susan Croll-Kalish	REG 1030A	7968

26693 7590 09/06/2006

REGENERON PHARMACEUTICALS, INC
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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,532	CROLL-KALISH ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, in part, 3-4, drawn to a method of identifying an agent capable of modulating CIRL3-L expression wherein an agent that inhibits CIRL3-L expression is an antisense molecule, classified in class 435, subclass 6.

II. Claims 1-2, in part, 3, 5, drawn to a method of identifying an agent capable of modulating CIRL3-L expression wherein an agent that inhibits CIRL3-L expression is an siRNA molecule, classified in class 435, subclass 6.

III. Claims 1-2, in part, 6-7, drawn to a method of identifying an agent capable of modulating CIRL3-L protein activity wherein the agent is a blocking antibody, classified in class 435, subclass 7.1.

IV. Claims 1-2, in part, 8, 9,10 in part, drawn to a method of identifying an agent capable of modulating CIRL3-L expression wherein the agent is an activator of CIRL3-L expression, classified in class 435, subclass 7.1.

V. Claims 1-2, in part, 8, in part, drawn to a method of identifying an agent capable of activating CIRL3-L protein activity, classified in class 435, subclass 4.

VI. Claims 11-13, drawn to an in vivo method of identifying an agent capable of modulating CIRL3-L protein comprising administering a test agent, classified in class 514, subclass 1.

VII. Claims 14-17, drawn to a non-human animal comprising an altered or deleted CIRL3-L gene wherein the non-human animal is characterized by exhibiting anxiety-related disorders, classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons: Inventions I, II, III, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The instant specification does not disclose that these methods would be used together. The method of identifying an agent capable of modulating a CIRL3-L expression wherein an agent that inhibits CIRL3-L expression is an antisense molecule (group I), the method of identifying an agent capable of modulating a CIRL3-L expression wherein an agent that inhibits CIRL3-L expression is an siRNA molecule (group II), the method of identifying an agent capable of modulating a CIRL3-L protein activity wherein the agent is a blocking antibody (group III), the method of identifying an agent capable of modulating a CIRL3-L expression wherein the agent is an activator of CIRL3-L expression (group IV), the method of identifying an agent capable of modulating a CIRL3-L protein activity (group V) and the in vivo method of identifying an agent capable of modulating a CIRL3-L protein comprising administering a test agent (group VI) are all unrelated as they

comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I, II, III, IV, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, II, III, IV, V and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I, II, III, IV, V and VI together.

Group VII and I –VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods I-VI do not use the transgenic animals of group VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

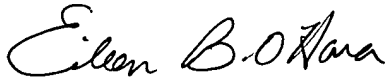
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.
Art Unit 1646
29 August 2006
Fax: 571-273-2922



EILEEN B. O'HARA
PRIMARY EXAMINER